EXHIBIT 10

Draft

September 5, 2003

Mr. Jim Jones
Director, Office of Pesticide Programs
Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Washington, D.C. 20460
Mail Code 7501C

Dear Mr. Jones;

This letter responds to the Environmental Protection Agency's (EPA) request for the Fish and Wildlife Service and National Marine Fisheries Service (collectively referred to hereafter as the Services) review and comment of the procedures EPA's Office of Pesticide Programs (OPP) uses to comply with the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 et seq.; ESA). These comments represent the Services' review of the procedures for the screening-level ecological risk assessments and species-specific risk assessments that EPA conducts for its pesticide registration program pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136 et seq.; FIFRA). In particular, this review evaluates EPA's screening-level risk assessments as a potential substitute for interagency consultations conducted pursuant to section 7(a)(2) of the ESA (16 U.S.C. 1536(a)(2)) and implementing regulations (50 CFR 402.13).

The Services restricted their review to those portions of the EPA's effects determinations portion of its Endangered Species Protection Program (ESPP) that are currently conducted by OPP's Environmental Fate and Effects Division (EFED) and the Field and External Affairs Division (FEAD). The Services expect to review the procedures of other divisions within OPP that are responsible for implementing the ESPP separately. In the absence of a comprehensive description of the processes OPP uses to make its endangered species effects determinations for the ESPP, the Services cannot reach final conclusions about the ESPP's ability to protect federally threatened and endangered species and critical habitat that has been designated for them (herein referred to collectively as listed resources).

These comments are organized in four general parts: (1) standards of review; (2) review of the current EPA procedures and recommendations specific to that review; (3) issues that will require additional discussion and procedures, and (4) conclusions.

Standards of Review

Interagency consultations and the documents they produce generally have to comply with the requirements of two separate statutes: the ESA and the Administrative Procedure Act (5 U.S.C. 701 et seq.). Interagency consultations conducted pursuant to section 7 of the ESA were established to help fulfill the purposes of the ESA, which are to *"provide a means whereby the ecosystems upon which endangered species and threatened species may be conserved, to provide a program for the conservation of such endangered species and threatened species..."* (16 U.S.C. 1531(b)).

EPA is aware that section 7 of the ESA contains several procedures to help conserve the ecosystems upon which endangered and threatened species depend and to conserve the species themselves. Section 7(a)(1) directs all Federal agencies, in consultation with and with the assistance of the Services, to utilize their authorities in the furtherance of the purposes of the ESA by carrying out programs for the conservation of listed resources. Section 7(a)(2) requires each Federal agency, in consultation with and with the assistance of the Services (acting on behalf of the Secretaries of Commerce and Interior, respectively), to *insure* that any action they authorize, fund, or carry out is not likely to jeopardize the continued existence of any listed species or result in the destruction or adverse modification of habitat designated as critical for that species. Section 7(a)(2) also requires the Services, action agencies, and applicants to use the best scientific and commercially available data to fulfill the requirement to insure that agency actions are not likely to jeopardize listed species or destroy or adversely modify critical habitat designated for listed species.

Since 1994, interagency consultations and the documents they generate have been reviewed using the "arbitrary and capricious" standard of the Administrative Procedure Act (5 U.S.C. 706; APA). When reviewing biological opinions for compliance with this standard, courts review the administrative records supporting biological opinions to determine if the Services (1) relied on factors which Congress has not intended the Services to consider; (2) failed to consider an important aspect of a problem or information that was relevant to the problem; (3) offered an explanation for our conclusion that runs counter to the evidence before the Services or is not so implausible that it could not be ascribed to a difference in view or the product of expertise; (4)

failed to conduct a reasoned evaluation of the best scientific and commercial data available and other relevant information; (5) failed to articulate a rational connection between the facts that were found and the conclusions we reached in our biological opinion.

If EPA proposes to substitute its screening-level risk assessments for interagency consultations that have traditionally involved the Services, we assume that any documents EPA produces must adhere to the same statutory standards that apply to Service documents. As a result, these standards formed the basis for many of the comments that follow.

Comments on and Recommendations for EPA's Existing Procedures

Comments on Current Procedures

The document prepared by EFED identifies the major assumptions that underlie EPA's screening level risk assessments, the consequences of relaxing or changing those assumptions, and the limitations of EPA's screening-level assessment process. EPA's disclosure helped the Services review the draft documents and made it clear that all three agencies share many common concerns about EPA's screening level risk assessments. The Services look forward to working with EPA to address common concerns like including information from published scientific journals, developing protocols and procedures for assessing the effects of pesticide formulations, inerts, surfactants, and mixtures; and for assessing the indirect effects of pesticide products on listed resources.

The comments that follow identify additional issues and concerns the Services believe require further discussion and development to improve the efficacy and reliability of EPA's existing risk assessment processes.

Modeling to Characterize Exposure

For aquatic organisms, such as fish and invertebrates, OPP usually estimates exposure using a tiered system of computer simulation models that calculate estimated environmental concentrations (EECs) in surface water using laboratory data that describe how fast the pesticide breaks down to other chemicals and how it moves in the environment (EFED document VI.B.1.b). The intent of the lower tiers is to provide a screening approach to estimate the concentration of a pesticide in water from sites that are highly vulnerable to runoff or leaching. The assessment moves to a more refined screening level assessment that is based on conditions more reflective of actual use site conditions, when levels of concern are exceeded using EECs based on generic assumptions (non-use site specific).

EPA's first screening model, GENEEC2 (GENeric Estimated Environmental Concentration), screens chemicals to identify ones which potentially pose sufficient risk to warrant more detailed modeling. The GENEEC2 calculates high end estimates of surface water concentrations of pesticides in a generic farm pond. If the results of this initial screen leads EPA to believe a more detailed analysis is warranted, EPA will conduct additional simulations with the PRZM-3 and EXAMS II model to provide more realistic, use-site specific EEC values.

EPA's documents appear to assume that there is "no risk of concern" to aquatic species if the endangered species level of concern (LOC) is not exceeded using GENEEC2 for exposure estimates. The Services recognize that there are many attributes of GENEEC2 that provide a generally conservative estimate of exposure. However, the Services do not agree that GENEEC2 is a sufficient screening tool for making ESA effects determinations for all aquatic species.

Although GENEEC2 may overestimate exposure for the majority of aquatic species, it is also likely that exposure is underestimated for several listed species because model assumptions are frequently not consistent with the attributes of critical habitat for listed species. For example, the model assumes the product is applied to a 10-hectare field and the aquatic habitat is a static 1-hectare pond 2 meters in depth. The volume of water in the pond relative to the size of the treatment area greatly influences the predicted concentration due to the dilution factor. A 10-

hectare field is relatively small considering some cropping patterns. More importantly, many listed species occupy static water bodies that contain a significantly smaller volume of water.

Failure to reconcile differences in habitat requirements of individuals species with model assumptions will likely result in an underestimation of risk for several species. For example, frog eggs and tadpoles are often found in shallow puddles near agricultural areas. Frogs, snakes, turtles, and other species often occupy muddy shoreline habitats or littoral zones that are significantly shallow compared to what is assumed using GENEEC2. The aquatic EEC derived from GENEEC2 calculations represents an initial average concentration for a pre-defined water body. However, the active ingredient will not initially be distributed homogeneously in water. Aquatic deposition through aerial drift or runoff will initially be greatest near application site (*i.e.*, the shoreline) and at the water surface. The result is that species that occupy shoreline habitats are not given the same level of protection as species that reside in deep water habitats. This point emphasizes the need to modify the exposure methods in the screening level assessment to be protective of all species and the need for EPA to do a more thorough job of incorporating species specific habitat considerations when conducting the "refined" species specific assessments.

EPA also suggests that a determination of effect may still be made if the initial screening estimates exceed endangered species LOCs by refining the exposure estimate using PRZM-3/EXAMS II. In refining the assessment, EPA selects input variables they consider to be conservative based on characteristics of major use areas (e.g. corn in Ohio, peaches in Georgia). However, these assumptions may not be conservative relative to everywhere the product is used and relative to listed resources. Additionally, PRZM/EXAMS assumes only 5 percent and 1 percent spray drift to the adjacent aquatic habitat for aerial and ground applications respectively. AgDrift simulations suggest that these assumptions underestimate risk under many application scenarios. Additionally, field trials designed to validate the AgDrift model have documented that AgDrift tends to underestimate drift under certain conditions. Further, during a Service meeting with EPA in February 2003, EPA acknowledged that based on comparisons with field trials, PRZM/EXAMS occasionally underestimates actual concentrations observed in the field

(typically due to underestimates of field persistence). Any assessment needs to take into account all geographic areas where the pesticide may be applied, not just major use areas.

In addition, the default spray drift assumptions are not sufficient to make ESA effect determinations for plants. Drift depends on several variables and many application scenarios will result in drift in excess of the default assumptions (1% and 5% for ground and aerial applications). It should be noted that listed plant species often occur in limited abundance and therefore point deposition calculations are more appropriate than averaging concentrations over relatively large downwind areas (*i.e.* one acre). Such comparisons are misleading and underestimate exposure to individual plants nearest the treatment site. In addition, the default assumptions do not reflect the higher drift values that have been determined using the AgDrift model.

For the purposes of characterizing exposure to terrestrial resources, EPA considers the dietary exposure route alone. Frequently, EPA human health assessments indicate compounds pose a risk to human health due to potential exposure from inhalation, dermal absorption, or consumption of contaminated water. These routes of exposure are pertinent to other terrestrial organism as well. However, the potential risks from these routes of exposure are not addressed even when they represent the most logical exposure pathway (*e.g.* inhalation exposure from soil fumigants, dermal exposures for amphibians who respire through their skin). EFED and FEAD need to incorporate the best available science to account for alternative routes of exposure in terrestrial species. Failure to consider all relevant exposure pathways may underestimate risk to listed resources.

The use of risk quotients (RQ) represent a direct comparison of effect thresholds to exposure estimates. EPA's proposal to compare risk quotients to levels of concern (LOCs) for effect determinations does not provide adequate protection for listed resources. The endangered species LOC has been presented as a threshold that will result in a very low probability of direct acute mortality. However, neither acute nor chronic LOCs or risk quotients account for

significant data gaps. The draft document indicates that the original derivation of the LOC referenced in Urban and Cook was incorrect (EFED page 64).

The current LOC derivation is based on what is considered a typical slope under probit analysis. A majority of the ecotoxicology studies submitted for registration do not have data that are probit transformed nor do they have a typical slope value of 4.5. The EFED draft demonstrates this point by providing the range of slopes for carbofuran (2-9) as a plausible range suggesting that the endangered species LOC of 0.1 would result in a probability of direct mortality of <2%. However, that determination is based on the slope range of a single compound. A review of the EPA's one-liner database suggests that consideration of slope data for all pesticides results in a greater range of slopes and a higher probability of direct mortality for some pesticides. This is especially the case where now there are a multitude of chemistries with different toxicological profiles and subsequent slope variations.

The Services recommend moving away from a standardized LOC comparison and using more conservative endpoints based on available toxicology studies. Depending on the quality of the data, EC_0s or NOECs can be used and compared to conservative exposure data to determine whether exposure values exceed thresholds. The use of EC_0s for example allows the risk assessment to be a function of the chemical and its properties as opposed to a one-size fits all level of concern. This type of approach is also consistent with the risk assessment process employed by other agencies and is consistent with some of the risk calculations that EFED currently uses for assessing risk to plants, as well as chronic risk to fish and wildlife. In addition to the use of EC_0s or NOEC values, EFED should utilize uncertainty factors when appropriate. This approach is commonly used within HED for assessing risk to pesticides and there are published uncertainty factors in the literature as well as other divisions of EPA for dealing with uncertainty in ecological risk assessments.

Recommendations for Improving EPA's Existing Procedures

The following recommendations offer an analytical structure that will allow OPP's ecological risk assessments to begin to meet the requisite APA standards of review and ESA section 7 substantive technical requirements. These recommendations use threatened and endangered salmonids as an example. They complement those procedures already in use by EPA, and are consistent with the EPA guidelines (EPA, 1998) For the most part, the emphasis of these recommendations is on the problem formulation phase since this process is critical for generating and testing hypotheses. In the case of ESA section 7 consultations, these hypotheses should focus on whether ecological effects from pesticide applications can occur and the degree of their effects on listed resources. In addition, these recommendations provide guidance for the analysis phase of ecological risk assessment. Specifically, we include recommendations for identifying the best available scientific and commercial data, evaluating scientific studies for data quality, and evaluating studies for their relevance to salmon-specific risk hypotheses.

The following recommendations are not meant to be comprehensive and use threatened and endangered salmonids as a case study. Problem formulations, hypotheses, and analyses will be different for other listed resources due to different life histories, biological requirements and ecosystem variations. The Services would expect to work with EPA to address other listed resources and raise more obscure issues at later dates. For example, the need remains to address stressor-response analyses and the risk characterization phase. These important components of ecological risk assessment and others will be influenced to a large extent by the scope and complexity of each future section 7 consultation.

1. Integrate Listed Species into the Problem Formulation Phase of Risk Assessment

In the problem formulation phase, the goal and scale of each risk assessment should be clearly defined. For all ESA effect determinations for pesticide registration actions, the goal is to evaluate the potential impacts of a pesticide registration action on the listed resources. This should include all relevant physical, biological and chemical structures within the listed resources environment that have the potential to affect the listed resources reproduction, numbers, and distribution. As required by the ESA, each assessment should consider adverse

effects on individual animals. The geographical and temporal scales of pesticide risk assessments should also be defined in the problem formulation phase.

2. Integrate Specific Assessment Endpoints that Reflect the Needs of Listed Resources

As defined in EPA's internal guidelines (EPA, 1998), assessment endpoints are "explicit expressions of the actual environmental value that is to be protected, operationally defined by an ecological entity and its attributes." Assessment endpoints reflect characteristics of salmonid health or salmonid habitat that can be functionally related to the survival, reproductive success, or migratory success of threatened or endangered species. Assessment endpoints that capture physical habitat processes and the availability of prey for salmonids are important because they recognize the potential for pesticides to have cascading adverse effects in riparian or aquatic systems.

The typical assessment endpoints that EPA uses for its screening level pesticide ecological risk assessments are reduced survival and reproductive impairment for both aquatic and terrestrial species from both direct acute and direct chronic exposures (EFED document VI.A.4). The Services agree that these assessment endpoints provide insight to risks at higher levels of biological organization (populations and community level). However, the status and trend of wild population's (as measured by intrinsic rates of increase) is controlled by more than births (fecundity schedules) and deaths (or survival rates) as reported by Tanner (1978), particularly for species with overlapping generations and population structure. Additional variables that can determine a species' persistence (or chances of extinction) are species' fecundity schedules, the age- or stage-structure of a population; age at maturity; time interval between repeated reproductive effort (iteroparity); behavioral responses that have population-level consequences, adverse effects on a species' immune responses, or changes in variance in any one of the variables (Burgman et al. 1993, Caswell 2001, Caughley and Gunn 1994, Morris and Doak 2002). All of these variables are potentially affected by exposure to pesticide formulations (Calow et al. 1997, Cook et al. 2003, Daniels and Allan 1981, de Guise et al. 1995, Edge and Schauber 2000, Fairchild et al. 1999, Gentile et al. 1982). As a result, EPA's risk assessments

should include endpoints that address these criteria, even if those endpoints are only considered qualitatively when the results of quantitative analyses are interpreted.

It is important to note that assessment endpoints may be different from measures, such as measures of effect. The ability of a salmon or steelhead to undergo smoltification and adapt to saltwater environments is an example of an assessment endpoint (or an "essential biological requirement"). The attributes of the endpoint, in turn, determine what to measure. In the example of saltwater adaptation, seawater challenge tests under different pesticide exposure conditions would be a measure of effect. Although assessment endpoints must be defined in terms of measurable attributes (e.g., egg quality and quantity are measurable attributes of reproductive success), the selection of endpoints does not depend on the ability to measure those attributes directly or on whether methods, models, or data are currently available. It is not necessary for methods to be standardized protocols, nor should assessment endpoints be selected simply because standardized protocols are readily available (EPA, 1998). In short, the selection of measures is dictated by the assessment endpoints and these, in turn, are directly linked to the goal of the risk assessment.

EPA should integrate specific assessment endpoints like the one listed below into the problem formulation phase of its screening level risk assessments. Although these examples are specific to the life histories of anadromous Pacific salmon and steelhead; they exemplify the scope and scale of endpoints that are appropriate to an assessment of the effects of pesticide products on threatened or endangered species based on the published, scientific literature. Pesticide products that adversely affects these biological or physical processes would be expected to adversely affect the survival, reproductive success, migratory and reproductive behavior of individual fish. As a result, those adverse effects would be expected to have negative effects on the viability or genetic integrity of wild populations. Examples of measures for each assessment endpoint are in parentheses.

- Acute mortality at any life history stage (LC_{50}).